K071137

510(k) SUMMARY

SONICATOR® PLUS 940, ME 940, K ( )

AUG - 1 2007

Submitter's Name: Mettler Electronics Corp.
Address: 1333 South Claudina Street
Anaheim, CA 92805

Telephone: 714-533-2221 x324
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Contact: Robert E. Fleming
Director, Regulatory Affairs

Date Prepared: September April 16, 2007

Proposed Device Name:

a. TRADE NAME: Sonicator® Plus 940 , Model ME 940
b. CLASSIFICATION NAME: Ultrasound and muscle stimulator (Sec. 890.5860, Product Code IMG)
c. COMMON NAME: Combination Ultrasound and Muscle Stimulator

Predicate Devices:

a. TRADE NAME: Sonicator® Plus 994, Model ME 994
b. 510(k) Number: K984142
c. TRADE NAME: Chattanooga Vectra Genesis
d. 510(k) Number: K031077

Description of Proposed Device:

The Sonicator® Plus 940 , Model ME 940 is a four-channel combination unit for therapeutic ultrasound and muscle stimulation. The microprocessor controlled Sonicator Plus 940 provides pre-modulated medium frequency and symmetrical biphasic waveforms with enhanced reliability and ease of use. In addition the Sonicator Plus 940 offers 1 and 3 MHz ultrasound using a variety of interchangeable applicators.

The four-channel Sonicator Plus 940 allows the clinician to utilize up to two different waveforms using four channels simultaneously. The clinician can choose between several different amplitude modulation options such as the surge, reciprocation and amplitude modulation *(interferential only, vector rotation).* The interferential and pre-modulated modes offer frequency modulation as well as a static frequency option.

The membrane panel provides both tactile and audio feedback when buttons are pressed. Blinking LED's guide the operator through the easy setup routine.

Large, soft-touch control knobs make adjusting power for ultrasound and stimulation easy to accomplish with no guesswork involved. A large LCD output display allows the clinician to monitor four channels simultaneously for four channel combination treatment protocols. It also allows the operator to adjust both channels of an interferential protocol simultaneously while monitoring the current.

The Sonicator Plus 940 can provide electrical stimulation only, ultrasound only and combination therapy with the pre-modulated, biphasic and medium frequency waveforms

Proposed Device Intended Use Statement:

Device Name: Sonicator® Plus 940, Model ME 940

Proposed Device Indications For Use (same as those for predicate device):

Therapeutic Ultrasound

1. Pain relief
2. Reduction of muscle spasm
3. Localized increase in blood flow
4. Increase range of motion of contracted joints using heat and stretch techniques.

Neuromuscular Stimulation

1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute post surgical pain (Interferential and Pre-modulated waveforms)
2. Temporary relaxation of muscle spasm (all waveforms)
3. Prevention of post-surgical phlebo-thrombosis through immediate stimulation of calf muscles (all waveforms)
4. Increase of blood flow in the treatment area (all waveforms)
5. Prevention or retardation of disuse atrophy in post-injury type conditions (all waveforms)
6. Muscle re-education (all waveforms)
7. Maintaining or increasing range of motion (all waveforms)

Biocompatibility Certification: Electrodes to be provided with this device are the same as those previously submitted since 1997 with Mettler Electronics Corp. devices: Sonicator Plus 992/994 (K984142); Sys*Stim 226 (K964028); Sys*Stim 294 (K984114); and Sonicator Plus 930 (K013192).

Comparison of Technological Characteristics Between Proposed and Predicate Devices:

Section 2

1.	510 K #	K	K031077
2.	Device Name	Sonicator Plus 940	Vectra Genesis
3.	Manufacturer	Mettler Electronics	Encore Medical *(Chattanooga Group)*
4.	Power Source	AC line	AC line or optional battery pack
	Line Current Isolation	Reinforced insulation	Not Stated in the Manual
	Max Leakage Current (µA)		
	Chassis	>50 under SFC	Not Stated in the Manual
	Electrodes	>50 under SFC	Not Stated in the Manual
5.	Number Of Output Modes	8	10
6.	Channel(s)	4	4
	Synchronous	1 & 2 or 3 & 4	1 & 2 or 3 & 4
	Reciprocal	1 & 2 or 3 & 4	1 & 2 or 3 & 4
	Other	Yes	Yes
7.	Constant Current	Yes	Optional
	Constant Voltage	No	Optional
8.	Software / Firmware / Microprocessor Control	Yes	Yes
9.	Automatic Overload Trip	Yes	Not Stated in the Manual
	Automatic Over Current Trip	Yes	Warning only, Overcurrent
10.	Automatic No Load Trip	Yes	Warning only, Bad electrode contact
11.	Automatic Shut Off	Yes	Yes
12.	Patient Override	No	Yes
	Control Method	On/Off, Hold or Stop	Patient interrupt switch
13.	Indicator Display		
	On / Off Status	Yes	Yes
	Voltage/Current Level	Yes	Yes
	Low Battery Indicator	N/A	Yes
14.	Timer Display:	0 – 60 minutes	0 – 60 minutes
15.	Standards		

ISO 14971 : 2000	Yes	Not Stated in the Manual
UL 2601-1	Yes	Not Stated in the Manual
CSA C22.2 NO 601.1-M90	Yes	Not Stated in the Manual
IEC/EN 60601-1	Yes	Yes
IEC/EN 60601-1-2	Yes	Yes
IEC/EN 60601-2-10	Yes	Yes
MDD 93/42/EEC, Annex II	Yes	Yes
16. Compliance with 21 CFR 898	Yes	Yes
17. Weight (lbs.)	11	7
18. Dimensions (in.) H x W x L	4.9 x 13.6 x x 10.5	8.8 x 11.375 x 12.75
19. Housing Materials & Construction	Metal Casing	Not stated in the Manual

Neuromuscular Stimulation, *Section 3*

510 K #	K	K031077
Device Name	**Sonicator Plus 940**	**Vectra Genisys**
Manufacturer	**Mettler Electronics**	**Encore Medical *(Chattanooga Group)***
Waveform		
EMS *(Premod, Vectra)*	Biphasic	Biphasic
TENS *(VMS, Vectra)*	Biphasic	Biphasic
Hi Volt	Pulsed Monophasic and Biphasic	Pulsed Monophasic
Russian	Biphasic	Biphasic
Shape		
EMS *(Premod, Vectra)*	Sinusidal	Sinusidal
TENS *(VMS, Vectra)*	Square	Square
Hi Volt	Twin spike	Twin spike
Russian	Gated Sinusoidal	Gated Sinusoidal
Max Output Voltage (V) ±20%		
500 Ω		
EMS *(Premod, Vectra)*	49	55
TENS *(VMS, Vectra)*	46	Not stated in the manual
Hi Volt	146	544
Russian	50	56.5
2 kΩ		

EMS *(Premod, Vectra)*	115	216
TENS *(VMS, Vectra)*	100	Not stated in the manual
Hi Volt	155	580
Russian	110	456
10 kΩ		
EMS *(Premod, Vectra)*	120	260
TENS *(VMS, Vectra)*	105	Not stated in the manual
Hi Volt	190	612
Russian	120	520
Max Output Current (mA) ±20%		
500 Ω		
EMS *(Premod, Vectra)*	98	200
TENS *(VMS, Vectra)*	90	200
Hi Volt	292	1088
Russian	100	113
2 kΩ		
EMS *(Premod, Vectra)*	57	108
TENS *(VMS, Vectra)*	50	Not stated in the manual
Hi Volt	78	290
Russian	55	114
10 kΩ		
EMS *(Premod, Vectra)*	12	26
TENS *(VMS, Vectra)*	10.5	Not stated in the manual
Hi Volt	19	61
Russian	12	26
Pulse Width Range		
EMS *(Premod, Vectra)*	500, 250, 200 µs	400, 250, 200 µs
TENS *(VMS, Vectra)*	100 - 600 µs	40 - 800 µs
Hi Volt	10 - 80 µs	5 µs
Russian	400 µs	400 µs
Frequency (Hz)		
EMS *(Premod, Vectra)*	2 kHz, 4 kHz, 5 kHz	2.5 kHz, 4 kHz, 5 kHz
TENS *(VMS, Vectra)*	0.5 - 250 Hz	1 - 200 Hz
Hi Volt	0.5 - 200 Hz	10 - 120 Hz
Russian	2.5 kHz	2.5 kHz
Beat Frequency (Hz)		

Interferential, 2-pole, *Premodulated*	1 - 250 Hz	1 - 200 Hz
Multiphasic Waveforms.....		
Symmetrical Phases?		
EMS *(Premod, Vectra)*	Yes	Yes
TENS *(VMS, Vectra)*	Yes	Yes
Hi Volt	Yes	No
Russian	Yes	Yes
Phase Duration		
EMS *(Premod, Vectra)*	250, 125, 100 µs	200, 125, 100 µs
TENS *(VMS, Vectra)*	50 - 300 µs	20 - 400 µs
Hi Volt	10 - 80 µs	Not stated in the manual
Russian	200 µs	200 µs
Net Charge	Zero	Zero (Not Hi Volt)
Symmetry	Symmetric	Symmetric (Not Hi Volt)
Method	Balanced	Balanced (Not Hi Volt)
Maximum Phase Charge (µC)		
500 Ω		
EMS *(Premod, Vectra)*	12.7	24.2
TENS *(VMS, Vectra)*	60	Not stated in the manual
Hi Volt	48	4.9
Russian	12.7	Not Stated in the Manual
Maximum Current Density		
(mA/cm², 500 Ω)		
EMS *(Premod, Vectra)*	0.02	3.84
TENS *(VMS, Vectra)*	0.002	Not stated in the manual
Hi Volt	0.002	59.08
Russian	2.9	Not stated in the manual
Maximum Power Density		
(W/cm², 500 Ω)		
EMS *(Premod, Vectra)*	0.089	0.149
TENS *(VMS, Vectra)*	0.037	Not stated in the manual
Hi Volt	0.035	32.14
Russian	0.121	Not stated in the manual
Burst Mode		

a. Pulses per burst		
EMS *(Premod, Vectra)*	N/A	N/A
TENS *(VMS, Vectra)*	7	7
Hi Volt	7	N/A
Russian	N/A	N/A
b. Bursts per second		
EMS *(Premod, Vectra)*	N/A	N/A
TENS *(VMS, Vectra)*	0.5, 0.7, 1, 2, 3, 4, 5, 6, 7	1 – 4
Hi Volt	0.5, 0.7, 1, 2, 3, 4, 5, 6, 7	N/A
Russian	0 – 100	20 – 100
c. Burst duration (ms)		
EMS *(Premod, Vectra)*	N/A	N/A
TENS *(VMS, Vectra)*	70	172
Hi Volt	120	N/A
Russian	2, 4, 6.....20	2, 4, 6,.....10
d. Duty Cycle (b x c)		
EMS *(Premod, Vectra)*	N/A	N/A
TENS *(VMS, Vectra)*	3.6 - 77.8 %	N/A
Hi Volt	6.3 % to 85.7 %	N/A
Russian	10, 20, 30, ...100%	10, 20, 30, 40, 50%
On Time (ms)		
EMS *(Premod, Vectra)*	1 - 99	5, 4, 10
TENS *(VMS, Vectra)*	1 - 30	5, 4, 10
Hi Volt	1 - 30	5, 4, 10
Russian	1 - 30	5, 4, 10
Off Time (s)		
EMS *(Premod, Vectra)*	1 - 99	5, 12, 10, 20, 30, 50
TENS *(VMS, Vectra)*	1 - 99	5, 12, 10, 20, 30, 50
Hi Volt	1 - 99	5, 12, 10, 20, 30, 50
Russian	1 - 99	5, 12, 10, 20, 30, 50

Pain Management, *Section 3*

510 K #	**K**	**K031077**
Device Name	**Sonicator Plus 940**	**Vectra Genisys**
Manufacturer	**Mettler Electronics**	**Encore Medical *(Chattanooga Group)***
Waveform		

Interferential, 4-pole	Biphasic	Biphasic
Interferential, 2-pole, *Premodulated*	Biphasic	Biphasic
TENS	Biphasic	Biphasic
Microcurrent	Biphasic and pulsed monophasic	Biphasic and pulsed monophasic
Shape		
Interferential, 4-pole	Sinusidal	Sinusidal
Interferential, 2-pole, *Premodulated*	Sinusidal	Sinusidal
TENS	Square	Square
Microcurrent	Square	Square
Max Output Voltage (V) ±20%		
500 Ω		
Interferential, 4-pole	48	57
Interferential, 2-pole, *Premodulated*	49	55
TENS	46	51
Microcurrent	0.38	0.48
2 kΩ		
Interferential, 4-pole	110	108
Interferential, 2-pole, *Premodulated*	115	216
TENS	100	191
Microcurrent	1.55	1.92
10 kΩ		
Interferential, 4-pole	120	260
Interferential, 2-pole, *Premodulated*	120	260
TENS	105	268
Microcurrent	7.5	9.8
Max Output Current (mA) ±20%		
500 Ω		
Interferential, 4-pole	96	114
Interferential, 2-pole, *Premodulated*	98	110
TENS	90	102
Microcurrent	0.760	0.960

2 kΩ		
Interferential, 4-pole	55	108
Interferential, 2-pole, *Premodulated*	57	108
TENS	50	96
Microcurrent	0.780	0.960
10 kΩ		
Interferential, 4-pole	12	26
Interferential, 2-pole, *Premodulated*	12	26
TENS	10.5	26.8
Microcurrent	0.750	0.980
Pulse Width Range		
Interferential, 4-pole	500, 250, 200 µs	400, 250, 200 µs
Interferential, 2-pole, *Premodulated*	500, 250, 200 µs	400, 250, 200 µs
TENS	100 - 600 µs	40 – 2000 µs
Microcurrent	1.25 ms - 1.67 s	1 ms - 10 s
Frequency (Hz)		
Interferential, 4-pole	2 kHz, 4 kHz, 5 kHz	2.5 kHz, 4 kHz, 5 kHz
Interferential, 2-pole, *Premodulated*	2 kHz, 4 kHz, 5 kHz	2.5 kHz, 4 kHz, 5 kHz
TENS	0.5 - 250 Hz	1 - 250 Hz
Microcurrent	0.3 - 400 Hz	0.1 – 1000 Hz
Beat Frequency (Hz)		
Interferential, 4-pole	1 - 250 Hz	1 - 200 Hz
Interferential, 2-pole, *Premodulated*	1 - 250 Hz	1 - 200 Hz
Multiphasic Waveforms.....		
Symmetrical Phases?		
Interferential, 4-pole	Yes	Yes
Interferential, 2-pole, *Premodulated*	Yes	Yes
TENS	Yes	Yes
Microcurrent	Yes	Yes
Phase Duration		
Interferential, 4-pole	250, 125, 100 µs	200, 125, 100 µs
Interferential, 2-pole,	250, 125, 100 µs	200, 125, 100 µs

Premodulated		
TENS	50 - 300 µs	20 – 1000 µs
Microcurrent	1.25 ms - 1.67 s	0.5 ms – 5 s
Net Charge	Zero	Zero
Symmetry	Symmetric	Symmetric
Method	Balanced	Balanced
Maximum Phase Charge (uC)		
500 Ω		
Interferential, 4-pole	12.7	25.0
Interferential, 2-pole, *Premodulated*	12.7	24.2
TENS	60	204
Microcurrent	75	Not Available
Maximum Current Density		
(mA/cm², 500 Ω)		
Interferential, 4-pole	2.9	3.98
Interferential, 2-pole, *Premodulated*	0.02	3.84
TENS	0.002	5.03
Microcurrent	0.00003	Not Available
Maximum Power Density		
(W/cm², 500 Ω)		
Interferential, 4-pole	0.121	0.16
Interferential, 2-pole, *Premodulated*	0.089	0.149
TENS	0.037	0.257
Microcurrent	0.000007	Not Available
Burst Mode		
a. Pulses per burst		
Interferential, 4-pole	N/A	N/A
Interferential, 2-pole, *Premodulated*	N/A	N/A
TENS	7	7
Microcurrent	N/A	N/A
b. Bursts per second		

Interferential, 4-pole	N/A	N/A
Interferential, 2-pole, *Premodulated*	N/A	N/A
TENS	0.5, 0.7, 1, 2, 3, 4, 5, 6, 7	1 - 4
Microcurrent	N/A	N/A
c. Burst duration (ms)		
Interferential, 4-pole	N/A	N/A
Interferential, 2-pole, *Premodulated*	N/A	N/A
TENS	70	172
Microcurrent	N/A	N/A
d. Duty Cycle (b x c)		
Interferential, 4-pole	N/A	N/A
Interferential, 2-pole, *Premodulated*	N/A	N/A
TENS	3.6 - 77.8 %	N/A
Microcurrent	N/A	N/A
On Time (s)		
Interferential, 4-pole	N/A	N/A
Interferential, 2-pole, *Premodulated*	N/A	5, 4, 10
TENS	1 - 30	N/A
Microcurrent	N/A	N/A
Off Time (s)		
Interferential, 4-pole	N/A	N/A
Interferential, 2-pole, *Premodulated*	N/A	5, 12, 10, 20, 30, 50
TENS	1 - 99	N/A
Microcurrent	N/A	N/A

Muscle Spasm, *Section 3*

510 K #	**K**	**K031077**
Device Name	**Sonicator Plus 940**	**Vectra Genisys**
Manufacturer	**Mettler Electronics**	**Encore Medical *(Chattanooga Group)***
Waveform		
Continuous DC	DC	DC
Shape		

Continuous DC	DC	DC
Max Output Voltage (V) ±20%		
500 Ω		
Continuous DC	10.2	2
2 kΩ		
Continuous DC	28	8
10 kΩ		
Continuous DC	34	41.6
Max Output Current (mA) ±20%		
500 Ω		
Continuous DC	20	4
2 kΩ		
Continuous DC	14	4
10 kΩ		
Continuous DC	17	4
Maximum Current Density (mA/cm², 500 Ω)		
Continuous DC	0.99	Not stated in the manual
Maximum Power Density (W/cm², 500 Ω)		
Continuous DC	0.0079	Not stated in the manual
On Time (s)		
Continuous DC	Controlled by probe	5, 4, 10
Off Time (s)		
Continuous DC	Controlled by probe	5, 12, 10, 20, 30, 50

Therapeutic Ultrasound

510 K #	**K**	**K031077**
Device Name	**Sonicator Plus 940**	**Vectra Genisys**
Manufacturer	**Mettler Electronics**	**Encore Medical *(Chattanooga Group)***
Power Source	AC Line	AC Line
Standards		
ISO 14971 : 2000	Yes	Not Stated in the Manual

UL 2601-1	Yes	Not Stated in the Manual
CSA C22.2 NO 601.1-M90	Yes	Not Stated in the Manual
IEC/EN 60601-1	Yes	Yes
IEC/EN 60601-1-2	Yes	Yes
IEC/EN 60601-2-5	Yes	Yes
FDA, 21 CFR 1050.10	Yes	Not Stated in the Manual
MDD 93/42/EEC, Annex II	Yes	Yes
Timer Accuracy:	± 3 %	Not stated in the Manual
Maximum Treatment Time:	30 minutes	30 minutes

Ultrasonic Generator Specifications

Frequency	1 MHz and 3 MHz, ± 5 %	1 MHz and 3.3 MHz, ± 5 %
Modes	Continuous and Pulsed	Continuous and Pulsed
Pulse Repetition Rate	100 Hz ± 10 %	100 Hz
Pulse Duration	0.5, 1.0, 2.0. 3.0, 4.0 and 5 ms (±10 %)	1 msec, 2 msec, 5 msec (± 20 %)
Temporal Peak/ average intensity ratio	2:1 ± 20 % at 50 % Duty Cycle 2.5 :1 ± 20 % at 40 % Duty Cycle 3.3:1 ± 20 % at 30 % Duty Cycle 5:1 ± 20 % at 20 % Duty Cycle 10:1 ± 20 % at 10 % Duty Cycle 20:1 ± 20 % at 5 % Duty Cycle	2:1 ± 20 % at 50 % Duty Cycle 5:1 ± 20 % at 20 % Duty Cycle 9:1 ± 20 % at 10 % Duty Cycle
Maximum output power	N/A 12 W for ME 9401 1.8 W for ME 9402	20 W for 10 cm^2 at 1 Mhz only 10 W for 5 cm^2 at 1 and 3.3 Mhz 2 W for 1 cm^2 at 3.3 Mhz only
Maximum intensity	2 W/cm^2 for continuous mode 3 W/cm^2 for pulsed mode	2.5 W/cm^2 for continuous mode 3 W/cm^2 for pulsed mode
Indication accuracy	± 20 %	± 20 %

Ultrasonic Applicator Specifications

Piezoelectric discs	Ultrasound transducer attached to a metal surface and patient contact through the metal	Ultrasound transducer attached to a metal surface and patient contact through the metal

Applicator Part Number	**ME 9401**

Frequency	1 MHz and 3 MHz ±5%	5 cm^2 1 MHz and 3.3 MHz
Effective Radiating Area	5.5 cm^2 (1 MHz) / 6.0 cm^2 (3 MHz)	ERA of 4 cm^2 for 5 cm^2 appl.
Maximum Beam Non–Uniformity Ratio	4.55 : 1 maximum	5:1 maximum

Applicator Part Number	**ME 9402**	
Frequency	1 MHz and 3 MHz	1 cm^2 at 3.3 MHz only
Effective Radiating Area	0.9 cm^2 (1MHz) / 0.9 cm^2 (3 MHz)	ERA is 0.8 cm^2 for 1 cm^2 appl.
Maximum Beam Non–Uniformity Ratio	4.68 : 1 maximum	5:1 maximum

Other Applicators	None	10 cm^2 and 2 cm^2 applicators
Frequency	N/A	1 MHz and 3 MHz for 10 cm^2 applicator and 3.3 MHz for 2 cm^2 applicator only
Effective Radiating Area	N/A	ERA of 8.5 cm^2 for 10 cm^2 applicator and ERA of 1.8 cm^2 for 2 cm^2 applicator
Maximum Beam Non–Uniformity Ratio	N/A	5:1 maximum

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 1 2007

Robert F. Fleming
Director, QA/RA
Mettler Electronics Corp.
1333 South Claudina St.
Anaheim, California 92805

Re: K071137
Trade/Device Name: Sonicator® Plus 940, Model ME 940
Regulation Number: 21 CFR 890.5860
Regulation Name: Ultrasound and muscle stimulator
Regulatory Class: Class II
Product Code: IMG, GZJ, LIH
Dated: July 3, 2007
Received: July 9, 2007

Dear Mr. Fleming:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for [signature] DEP D.A. 8.1.07

Mark N. Melkerson, M.S.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K071137

Device Name: Sonicator® Plus 940 (ME940)

Indications for Use:

Therapeutic Ultrasound

Application of therapeutic deep heat for the treatment of selected sub-chronic and chronic medical conditions such as;

1. Relief of pain, muscle spasms and joint contractures:
2. Relief of pain, muscle spasms and joint contractures that may be associated with:
   - Adhesive capsulitis
   - Bursitis with slight calcification
   - Myositis
   - Soft tissue injuries
   - Shortened tendons due to past injuries and scar tissues
3. Relief of pain, muscle spasms and joint contractures resulting from:
   - Capsular tightness
   - Capsular tightening

4-Pole Interferential, 2-Pole Interferential, TENS and Microcurrent waveforms

1. Symptomatic relief of chronic intractable pain
2. Post-traumatic pain
3. Post-surgical pain

EMS, TENS, Hi Volt and Russian waveforms

1.Relaxation of muscle spasms
2. Increase local blood circulation
3. Prevention or retardation of disuse atrophy
4. Muscle re-education
5. Maintaining or increasing range of motion
6. Immediate post surgical stimulation of calf muscles to prevent venous thrombosis

DC (Direct Current)

Relaxation of muscle spasms

(PLEASE DO NOT WRITE BELOW THIS LINE — CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrent of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K071137

Prescription Use ✔ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)